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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,374

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Joseph C. Rongione

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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

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1621

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,374	Applicant(s) RONGIONE ET AL.	
	Examiner YATE K. CUTLIFF	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/01/2006, 3/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 - 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Strube et al. (US 6,762,313).

3. The rejected claims disclose a process for refining a conjugated linoleic acid-containing material comprising: distilling a first ester stream containing esters of conjugated linoleic acids using distillation apparatus; and producing a second ester stream enriched in the esters of conjugated linoleic acids.

4. Strube et al. discloses the distillation of a transesterification reaction mixture containing esters of linoleic acids and wherein the palmitic acid content can be reduced and the linoleic acid content increased by distillation of the product. The distillation is carried out the first time at 100 to 300 mbar of pressure, which is 75mmHg to 225mmHg of pressure, and a fractionating column is used. During the first distillation step, excess ethanol is removed. Another distillation step, fractional distillation may be applied. Additionally, unconjugated linoleic acid (C18:0) compounds are removed. (see column 3, lines 8-35, Example 1, and column 4, table 1).

5. Claims 21 and 22 rejected under 35 U.S.C. 102(b) as being anticipated by Strube et al.

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6. Strube et al. discloses a composition enriched with refined conjugated linoleic acid esters. (see column 4, Table 1).

Applicant is reminded that claims 21 and 22 are claimed in a Product-by-Process format. The PTO takes the following position with respect to Product-by-Process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garner, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,743,931), Baltes et al. (US 3,162,658) and Strube et al.

11. The rejected claims cover, inter alia, a process to produce a refined conjugated linoleic acid-containing material, comprising: transesterification of a linoleic acid-containing oil, generating linoleic acid esters in composition; isomerization of the composition forming a first stream; and distillation of the first stream to form a second stream of enriched linoleic acid esters.

Rejected claims 10 - 15 disclose the isomerization catalyst, and isomerization reaction temperature. Rejected claims 9 and 17-20 are drawn to the work up and optimization of the process. Rejected claim 16 discloses the various linoleic acid containing oils used in the process.

Saebo et al. discloses the process for the manufacturing of conjugated linoleic acid esters that are derived from sunflower oil, safflower oil, or corn oil. Saebo et al uses a tightly controlled nonaqueous alkali isomerization process. The alkyl esters of linoleic acid derived from the oils set out above, in the process the oils are reacted in the presence of an alkali alcoholate catalyst and a small amount of a suitable solvent (e.g. methanol or ethanol). (see column 9, lines 35-37, & lines 40-45). The isomerization process is accomplished by reacting the esters of the linoleic acid produced in the esterification step, with a quantity of monohydric alcohol (e.g. methanol, ethanol, propanol or butanol) and an alcoholate catalyst such as sodium or potassium ethoxide or their methyl, butyl, or propyl counterparts. (see column 10, lines 39- 47). The isomerization reaction proceeds at a temperature of 100 to 130°C, preferably at about 111 to 115°C. (see column 10, lines 55-56). Prior to conjugation (isomerization) the esterification product is distilled to remove monoesters obtained by alcoholysis. (see column 10, lines 36-38). The isomerization reaction produces conjugated linoleic acid alkyl esters. (see column 10, lines 58-59). Example 1 in column 15 sets out the steps for large scale batch production of conjugated safflower fatty acid methyl esters. According to Example 1 the process may be divided into two steps, methanolysis (transesterification) and conjugation (isomerization); and it is shown that the both process are performed in one reaction vessel to produce the ethyl esters.

Saebo et al. fails to disclose the process including a distillation step after the formation the linoleic acid esters by isomerization; and the distillation step being preformed at reduced pressure; the use of a calcium alkoixde salt; the catalyst is a

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conjugated alcohol of the alkoxide; the use of soybean oil, cotton seed oil, grape seed oil, and sesame oil; and the use of a dual reaction zone apparatus.

Baltes et al. discloses an isomerization process for the production of conjugated poly-ethenoid acids and uses the following alkali metals for the alcoholate catalyst: cesium, rubidium, potassium, sodium, lithium, magnesium and zinc. (see column 2, lines 39-45). It is stated that organic alkali metal compounds can be used as catalyst. Also, in Example 1, dried potassium methyllate (solid) is used. Like Seabo et al. Baltes et al fails to list calcium, however, based on the periodic family both references include, one skilled in the art would have been motivated to vary the reaction process, such as by using the calcium as a cation for the alkoxide as a matter of choice based on such factors as the success of other family members in the isomerization reaction. Baltes states that the isomerization process can be used with the methyl esters of soya bean fatty acids, cotton seed fatty acids and linseed oil fatty acids.

Strube et al. discloses the distillation, at reduced pressure, of a transesterification reaction mixture containing esters of linoleic acids and that enriches the linoleic acid ester content in the distillation of the product. Applicant is directed to the discussion of Strube et al. in paragraph 4. Further, Saebo et al. teaches that a distillation step can be used after transesterification (alcoholysis) and before conjugation (isomerization) to glycerol and any monoesters. Therefore, based on these teachings, and since it is the intent of both references to increase the amount linoleic acid ester produced in the end product, one of ordinary skill in the art would have been motivated to add an additional

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distillation step at the industrial level to further tweak the steps in order to increase the purity.

With regard to the use of dual reaction zones for the transesterification and isomerization step, based on the teachings of Saebo et al., the use of dual reaction zones, such as a first reaction zone and a second reaction zone would appear to be within the purview of the ordinary artisan skill in industrial manufacturing of fatty acid alkyl esters. A skilled artisan would be motivated to change the conditions such as separate reaction apparatus in order to optimize the process.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce refined esters of conjugated linoleic acid, as suggested by Saebo et al. and Baltes et al. and then further refine the isomerization product by using distillation such as the distillation process suggested by Strube et al. to further refine the ester of linoleic acid and remove any remaining unconjugated linoleic acid esters, and produce the instant invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 - 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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